**Canadian Clinical Drug Data Set (CCDD)**

**Répertoire canadien des médicaments (RCM)**

**Maintenance Tips for CCDD French**

**B. Prime May 2021**

**Background**: CCDD French (RCM) was launched in December 2019 and is now maintained in harmony with CCDD English. There is no lag between English and French releases, which occur in the first 2 weeks of each month (usually first 7 days). The version of record is CCDD English, and RCM mirrors CCDD in a consistent manner.

**Documentation**

**Editorial Guidelines**

* Editorial guidelines for CCDD were developed in English (version of record) and translated into French
* Reside on the CCDD page of Canada Health Infoway’s Infoscribe website: (<https://infoscribe.infoway-inforoute.ca/display/CCDD/Canadian+Clinical+Drug+Data+Set>)
* Source documents maintained on Google Drive, then uploaded to InfoScribe: CCDD-Infoway QA Team/Current Active Files/CCDD Editorial Guidelines/Editorial Guidelines: FINAL EN and FR (<https://drive.google.com/drive/folders/1kY1wOzq9lke4bFaPSPPoT71tv1YggmuF>).
* Updates to English editorial guidelines must be translated into French in time to be published with the English version.

**Release Notes**

* Published in English and French in conjunction with each monthly release. These reside on the same InfoScribe CCDD page as the Editorial Guidelines.

**Translation Resources**

Documentation (e.g., Editorial Guidelines) has been translated at Health Canada and reviewed by members of the CCDD team. A bilingual glossary of CCDD terms appears at the end of this document ([Appendix I](#1aycl5nqrrtt)). [Appendix II](#AppenII) was created for the specialized terms used in immunization products.

**Managing New/Updated CCDD Concepts**

**Therapeutic Moiety (TM)**

***Fraction Thérapeutique (FT)***

* FR ingredient names are based on the chosen English term for CCDD.
* Might be same as in DPD, but not if English CCDD ingredient name is different, e.g., if DPD uses USAN or other name and decision for CCDD is to use INN for a particular ingredient
* DPD French is the principle reference source for ingredient names; when there is uncertainty whether it is correct (e.g., spelling/accents) in DPD, useful resources include:
  + *INESS (*[*https://www.inesss.qc.ca/en/publications/inessss-guides.html*](https://www.inesss.qc.ca/en/publications/inessss-guides.html)*)*
  + *RAMQ (*[*http://www.ramq.gouv.qc.ca/fr/publications/citoyens/publications-legales/Pages/liste-medicaments.aspx*](http://www.ramq.gouv.qc.ca/fr/publications/citoyens/publications-legales/Pages/liste-medicaments.aspx)*)*
  + *French sites (*[*http://base-donnees-publique.medicaments.gouv.fr/*](http://base-donnees-publique.medicaments.gouv.fr/)*,* [*http://agence-prd.ansm.sante.fr/php/ecodex/index.php*](http://agence-prd.ansm.sante.fr/php/ecodex/index.php)*)*
  + *Health Canada drug nomenclature: PDSC committee; Office of Science; prescription drug list (*[*https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list.html*](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list.html)*)*
  + *FR Product Monograph\**
  + *Label (via Docubridge)\**

\* *Ingredient names in product* *monograph and label are sometimes inconsistent with DPD. On a case-by case basis, it may be necessary to inform/engage with TBD/DPD/BRDD to address issues.*

**Manufactured Product (MP) and Nonproprietary Therapeutic Product (NTP)**

***Produit manufacturé (PM) et Produit thérapeutique commun (PTC)***

Sample MP with hydrate/solvate:

EN: MINT-PAROXETINE (paroxetine (paroxetine hydrochloride hemihydrate) 30 mg oral tablet) MINT PHARMACEUTICALS INC

FR: MINT-PAROXETINE (paroxétine (chlorhydrate de paroxétine hémihydraté) 10 mg comprimé oral) MINT PHARMACEUTICALS INC

1. Brand name:

* Brand name and manufacturer are identical in English and French MP (see also 3rd bullet)
* CCDD brand names are exactly as they appear in DPD - all upper case, NOT translated to French if in English in DPD
* Note: there is sometimes descriptive text as part of a brand name (e.g., CHEWABLE TABLET) which is usually in English but sometimes in French (e.g., COMPRIMÉ CROQUABLE). Whatever the language for the descriptive text, there is usually only one brand name in DPD. Rarely, there is a different FR brand name in DPD. In May 2021 a discussion began re. tweaking the CCDD generation to grab the FR brand name from DPD, IF one exists. Currently, the generation grabs the EN brand name for both EN and FR MPs. No decision as of May 12 2021

2. Ingredient(s):

* CCDD generation derives ingredient names via text-string match (including case match) between ingredient name in DPD and the DPD Ingredient field in the CCDD ingredient stem table; ingredient names in TMs, NTPs and MPs are generated from the values in the row of the stem table that corresponds to that initial text match. This means that except for hydrates/solvates (see third bullet) the DPD ingredient name in CCDD FR is NOT derived directly from DPD FR, but from the value in the stem table (which should be a faithful representation of the FR ingredient name in DPD).
* both EN and FR ingredient names in the ingredient stem table maintained using the HC Drupal tool
* MP derives ingredient name from NTP Ing/NTP Ing FR field, except when HYDRATE field = TRUE, in which case both EN and FR ingredient names come **directly from DPD** and include the hydrate or solvate portion of the name.
* French names are *not* altered to place the active moiety at the beginning of the name (e.g., *chlorhydrate de paroxétine* NOT *paroxétine, chlorhydrate de*)
* In multi-ingredient NTPs, ingredients are in alpha order in English. For consistency, corresponding ingredients in the French NTP are in the same order as in the English NTP, even though they will often not be in alpha order in French.

3. Strength:

* Expressed as in English
* derived from DPD strength and UP table; if calculation flag = Y, DPD strength is multiplied by container size to give total amount (e.g., if strength in DPD is 10 mg/mL, vial size is 10 mL, and calculation flag = Y, NTP strength will be 100 mg per 10 mL)
* Numerator strength units are often SI terms (e.g., 10 **mg** per mL, 1 **g** per vial), and are therefore the same in EN and FR; noted exception: unit = unité (always singular), e.g., 100 **unit** per mL, 100 **unité** par mL
* Decimals will be expressed as commas in French (e.g., 0,5 %)
* Strength denominators are much more variable. Noted French terms that were changed/standardized in DPD due to input from CCDD team include:
  + vial = *fiole*
  + bag = *sac*
  + actuation = *actionnement*
  + bottle = *bouteille*

Note: All terms used in DPD were evaluated and standardized for CCDD. Brand new terms occurring in DPD strength numerators or denominators will need to be validated for CCDD. Full table of numerator/denominator terms: “French CCDD: DPD Strength Units (numerators & denominators) March 22 2019” (<https://docs.google.com/spreadsheets/d/1B8NGFlPxJ_4mkJavy0F-fx4mn6QXffsCVbbpBg0216E/edit#gid=1074666025>) BARB: Move to Y drive

4. Dose form:

* Official dosage form terms for CCDD (EN and FR) can be found in Github
* Generated from a combination of DPD route and dosage form. Each combination of DPD route and dosage form corresponds to an approved CCDD dose form, documented in the NTP Dose Form Map (source file maintained in Drupal).
* If a new dose form is added to the table, the French term will need to be validated. If the corresponding French EDQM term is not ideal for the Canadian healthcare context, consult with appropriate individuals to determine optimal term, e.g., Margaret Taylor-margaret.taylor@canada.ca) or French Advisory Group members (if still OK to do so - check with Seema Nayani at Infoway [snayani@infoway-inforoute.ca](mailto:snayani@infoway-inforoute.ca)). See [Appendix III](#92z92akmb70i) for contact information.

5. Unit of Presentation:

* The unit of presentation is added to the NTP in certain cases, such as injectables. For a full explanation, refer to the Editorial Guidelines.
* When the strength in DPD does not display according to CCDD standards, an entry is required in the Unit of Presentation source table (maintained through Drupal tool) to make the product display properly in CCDD, e.g.,
  + 100 unit per mL solution for injection 10 mL **vial**
  + 300 mcg per 1.5 mL solution for injection 3 mL **pen**
  + 500 mg per 1 mL solution for injection **syringe**.
* There is a list of acceptable terms for unit of presentation in CCDD, in English and French, which display in drop-down menus when a new row is added to the unit of presentation table.
* If a new term (e.g., due to marketing of a novel product) is added in English, an acceptable French version of the term will need to be added. See “4. Dose form” for a list of potential resources in case the best term is not a straightforward choice.

**Appendix I**

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| --- | --- | --- | --- |
| **CCDD Terminology – EN/FR** | | | |
| **English Term** | **EN Abbr.** | **French Term** | **FR Abbr.** |
| Canadian Clinical Drug Data Set | CCDD | Répertoire canadien des médicaments *(m)* | RCM |
| administrable dose form |  | forme pharmaceutique pour administration *(f)* |  |
| basis of strength substance | BoSS | substance mesure de la concentration |  |
| coded attribute |  | attribut codé *(m)* |  |
| combination products |  | produits mixtes *(m)* |  |
| concept |  | concept (*m*) |  |
| conventional  (e.g., irinotecan (conventional) |  | classique (p. ex. irinotecan (classique) |  |
| deprecated |  | déprécié |  |
| device |  | instrument *(m)* |  |
| device NPT |  | instrument de produit thérapeutique commun *(m)* |  |
| dose (dosage) form |  | forme pharmaceutique *(f)* |  |
| formal name |  | nom officiel *(m)* |  |
| formal name pattern |  | modèle de nom officiel *(m)* |  |
| ingredient |  | substance *(m)* |  |
| intended audience |  | public cible *(m)* |  |
| interchange terminology |  | terminologie des échanges *(f)* |  |
| manufactured dose form |  | forme pharmaceutique manufacturé *(f)* |  |
| manufactured product | MP | produit manufacturé *(m)* | PM |
| nonproprietary therapeutic product | NTP | produit thérapeutique commun *(m)* | PTC |
| per actuation |  | par actionnement |  |
| precise active ingredient |  | substance active précise *(f)* |  |
| release |  | version *(f)* |  |
| scope |  | portée *(f)* |  |
| special groupings |  | regroupements spéciaux *(m)* |  |
| status |  | état *(f)* |  |
| strength |  | concentration *(f)* |  |
| substance-strength set |  | ensemble substance-concentration *(f)* |  |
| technical specification |  | spécification technique *(f)* |  |
| therapeutic moiety | TM | fraction thérapeutique *(f)* | FT |
| unit of presentation |  | unité de présentation *(m)* |  |

**Appendix II**

**Glossary of Terms for Immunization Products**

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| --- | --- | --- | --- |
| **CCDD: Immunization Product Terminology EN/FR** | | | |
| **English Term** | **EN Abbr.** | **French Term** | **FR Abbr.** |
| diphtheria toxoid |  | anatoxine diphtérique |  |
| pertussis acellular |  | coqueluche acellulaire |  |
| typhoid polysaccharide |  | typhoïde polysaccharidique |  |
| live attenuated |  | vivant atténué |  |
| herpes zoster (as a condition/infection rather than virus name) |  | zona |  |
| recombinant |  | recombinant(e) |  |
| surface antigen |  | antigène de surface |  |
| subtype |  | soustype |  |
| serotype |  | sérotype |  |
| polyribosylribitol phosphate capsular polysaccharide |  | polysaccharide capsulaire polyribosylribitolphosphate |  |
| strain |  | souche |  |
| surface antigen |  | antigène de surface |  |
| capsular polysaccharide |  | polysaccharide capsulaire |  |
| capsid protein |  | protéine de capside |  |
| split virioin |  | à virion fragmenté |  |
| binding protein fusion protein |  | protéine hybride de protéine de liaison |  |
| neisserial heparin binding antigen fusion protein |  | protéine hybride de protéine méningococcique de liaison à l’héparine |  |
| capsular oligosaccharide |  | oligosaccharide capsulaire |  |
| filamentous hemagglutinin |  | hémagglutinine filamenteuse |  |
| serovar |  | sérovar |  |
| colony forming units | CFU | unités formant des colonies | UFC |
| plaque-forming units |  | unités formant des plaques | UFP |
| recombinant adenovirus vector |  | vecteur adénoviral recombinant |  |
| viral particules | vp | particules virales | (not abbrev in FR) |

**Appendix III**

|  |  |  |
| --- | --- | --- |
| **CCDD French Advisory Group**  **Membres du groupe consultatif francophone** | | |
| **Nom** | **Organisme** | **Addresse courriel** |
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